



DEPARTMENT OF HEALTH AND HUMAN SERVICES

9/28/01 JEP
Food and Drug Administration
New Orleans District Office
6600 Plaza Drive, Suite 400
New Orleans, LA 70127

September 24, 2001

VIA FEDERAL EXPRESS

FACILITY ID# 223540

Barry Michaels, Administrator
Selma Regional Medical Center
1023 Medical Center Parkway
Selma, AL 36701

Warning Letter No. 01-NSV-39

Dear Mr. Michaels:

Your facility was inspected on September 5, 2001 by a representative of the State of Alabama on contract to the Food and Drug Administration (FDA). This inspection revealed that your facility failed to comply with the Quality Standards for Mammography (Standards) as specified in Title 21, Code of Federal Regulations (CFR), Part 900.12, as follows:

Level 2 (Repeat Finding)

3 of 6 random reports reviewed did not contain an acceptable assessment category for site Selma Regional Medical Center

This finding was also noted during your September 22, 2000 inspection. You responded to the findings of this inspection with an undated letter indicating that the physician who dictated the noncompliant reports was educated to the correct procedure and terminology when dictating mammography reports.

The inspector who conducted your inspection of September 5, 2001 submitted to this office a copy of three mammography reports for review. Two of these submitted reports were dictated and electronically signed by [REDACTED], and lacked the required assessment categories.

Level 2

Failed to produce documents verifying that the interpreting physician, [REDACTED] (14 CMEs in 36 months) met the continuing education requirement of having taught or completed at least 15 category 1 continuing medical education units (CMEs) in mammography in 36 months.

[REDACTED] cannot lawfully read mammograms independently until he obtains the necessary CME credits to return him to compliance with the regulations.

These specific deficiencies appeared on the Post Inspection Report, which was given to your facility by the state inspector along with instructions on how to respond to these findings. These deficiencies may be symptomatic of serious problems that could compromise the quality of mammography at your facility and potentially overexpose both patients and employees involved with mammography.

It is your responsibility to ensure adherence to each requirement of the Mammography Quality Standards Act of 1992 (MQSA) and FDA's regulations. You are responsible for investigating and determining the cause of these deficiencies as identified and to promptly initiate permanent corrective action.

If you fail to properly address these deficiencies, FDA may, without further notice, initiate regulatory action. Under MQSA, FDA may:

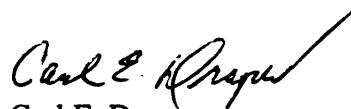
- impose civil money penalties on a facility of up to \$10,000 for each failure to substantially comply with, or each day of failure to comply with the Standards.
- suspend or revoke a facility's FDA certificate for failure to comply with the Standards
- seek an injunction in federal court to prohibit any mammography activity that constitutes a serious risk to human health.

Within fifteen (15) working days after receiving this letter, you should notify FDA in writing of each step that your facility is taking to prevent the recurrence of any similar violations.

If your facility is unable to complete these corrective actions within 15 working days, you should state the reason for the delay and the time within which the corrections will be completed.

Your reply should be directed to Joseph E. Hayes, Compliance Officer, Food and Drug Administration, 297 Plus Park Boulevard, Nashville, Tennessee 37217, telephone 615/781-5389, extension 125, with a copy to the State of Tennessee. Should you have questions regarding this letter or MQSA standards, you may call Karen Smallwood, Radiation Specialist, at 615/781-5380, extension 144.

Sincerely,



Carl E. Draper
Director, New Orleans District

CED:KRS:man

cc: State of Alabama
Dept. of Public Health
Office of Radiation Control
P.O. Box 303017
Montgomery, AL 36130-3017
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